



Version with Markings to Show Changes Made

In the Specification

Page 11, first paragraph (AMENDED)

coating layer containing polyethylene glycol, and still yet further coated with mannitol, to give fine granules, which are mixed with additives and shaped. The above-mentioned "enteric coating layer" includes, for example, aqueous enteric polymer substrates such as cellulose acetate phthalate (CAP), hydroxypropylmethyl cellulose phthalate, hydroxymethyl cellulose acetate succinate, methacrylic acid copolymers (e.g., Eudragit L30D-55 (trade name; produced by Rohm), Colicoat MAE30DP (trade name; produced by BASF), **[Polykid] Polyquid PA30** (trade name; produced by San-yo Chemical)), carboxymethylethyl cellulose and shellac; sustained-release substrates such as methacrylic acid polymers (e.g., Eudragit NE30 D (trade name), Eudragit RL30D (trade name), Eudragit RS30D (trade name), etc.); water-soluble polymers; plasticizers such as triethyl citrate, polyethylene glycol, acetylated monoglycerides, **[triacetine] triacetin** and castor oil; and mixtures thereof. The above-mentioned "additive" includes, for example, water-soluble sugar alcohols (e.g., sorbitol, mannitol, **[multitol] maltitol**, reduced starch saccharides, xylitol, reduced **[paratinose,] palatinose**, erythritol, etc.), crystalline cellulose (e.g., Ceolas KG 801, Avicel PH 101, Avicel PH 102, Avicel PH 301, Avicel PH 302, Avicel RC-591 (crystalline cellulose carmellose sodium)), low-substituted hydroxypropyl cellulose (e.g., LH-22, LH-32, LH-23, LH-33 (Shin-Etsu Chemical) and mixtures thereof); binders, souring agents, bubbling agents, sweetening agents, flavorings, lubricants, coloring agents, stabilizers, excipients, disintegrants etc. are also used.

Lansoprazole (racemate) (34.2 g) was dissolved in 2-propanol (1,710 ml) and hexane (1,140 ml) containing triethylamine (0.2%) and fractionated by HPLC (column: CHIRALCEL OD 50 mm dia. X 500 mm, temperature: room temperature, mobile phase: hexane/2-propanol = 85/15, flow rate: 60 ml/min, detection wavelength: 285 nm, [1 shot] single injection: about 300 mg) to isolate the individual optical isomers. Fractions of an optical isomer of shorter retention time were combined and concentrated; the individual lots were combined and dissolved in ethanol (250 ml); after triethylamine (3 ml) was added, the solution was filtered through a 0.45  $\mu$ m filter. After the filtrate was concentrated, hexane was added, and the filtrate was again evaporated to dryness to yield

In the Claims

3. (Once Amended) A crystal [according to Claim 2] of (R)-2-(((3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl)methyl)sulfinyl)-1H-benzimidazole wherein the X-ray powder diffraction analysis pattern has characteristic peaks at interplanar spacings (d) of 11.68, 6.77, 5.84, 5.73, 4.43, 4.09, 3.94, 3.89, 3.69, 3.41 and 3.11 Angstrom.
4. (Once Amended) A pharmaceutical composition which comprises the crystal according to Claim [1] 3 and a pharmaceutically acceptable excipient, carrier or diluent.
6. (Once Amended) A method for treating or preventing digestive ulcer in a mammal in need thereof which comprises administering to said mammal an effective amount of the crystal according to Claim [1] 3 with a pharmaceutically acceptable excipient, carrier or diluent.

7. (Twice Amended) A method for manufacturing a pharmaceutical composition for treating or preventing digestive ulcer comprising formulating the composition with the crystal [claimed in]  
of Claim [1] 3.



## REMARKS

### I. Amendments

Claims 3, 4, 6 and 7 have been amended; new claims 8-11 have been added and claims 1, 2 and 5 have been canceled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed. Specifically, support for new independent claim 8 may be found in Example 3 on page 23, line 4 – page 24, line 5 *inter alia*.

Typographical and grammatical errors have also been corrected throughout the specification.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned “Version with Markings to Show Changes Made”.

No change of inventorship is necessitated by this amendment.

### II. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) over WO 96/17077

Claims 1, 2 and 4-7 have been rejected under 35 U.S.C. Sec. 102(b) as anticipated by WO 96/17077. By this amendment, claim 3 has been made an independent claim, claims 1, 2 and 5 have been cancelled and the dependencies of claims 4, 6 and 7 have been modified from dependency on claim 1 to dependency on claim 3. Therefore Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 102(b) over WO 96/17077.

### III. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) over CA 124:3311460

Claims 1, 2 and 4-7 have been rejected under 35 U.S.C. Sec. 102(b) as anticipated by CA 124:3311460. By this amendment, claim 3 has been made an independent claim, claims 1, 2 and 5 have been cancelled and the dependencies of claims 4, 6 and 7 have been modified from dependency on claim 1 to dependency on claim 3. Therefore

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 102(b) over CA 124:3311460.

#### **IV. Discussion of the Rejection under 35 U.S.C. Sec. 103(a)**

Claims 1, 2 and 4-7 have been rejected under 35 U.S.C. Sec. 103 (a) as being unpatentable over WO 98/21201 or CA 127:336721 or CA 127:362535 or EP 174 726 or EP 302 720 in view of CA 124:331460.

By this amendment, claim 3 has been made an independent claim, claims 1, 2 and 5 have been cancelled and the dependencies of claims 4, 6 and 7 have been modified from dependency on claim 1 to dependency on claim 3.

Therefore, Applicants respectfully request withdrawal of the Sec. 103(a) rejection.

#### **V. Discussion of the Objection to Claim 3**

The Examiner has indicated that claim 3 would be allowable if re-written in independent form including all of the limitations of the base claim and any intervening claims.

By this amendment, claim 3 has been made an independent claim including the base claim. In addition, claims 4, 6 and 7 have been re-written as dependent claims of claim 3. Therefore, Applicants submit that claim 3 and its dependent claims are now in condition for allowance, so Applicants respectfully request withdrawal of the objection to claim 3.

VI. Conclusion



Reconsideration of the claims as amended and allowance is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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